The correspondence section is a public forum and, as such, is not peer-reviewed. EHP *is not responsible for the accuracy, currency, or reliability of personal opinion expressed herein; it is the sole responsibility of the authors.* EHP *neither endorses nor disputes their published commentary.*

Good Laboratory Practices and Safety Assessments: Another View

doi:10.1289/ehp.0901755

In a letter responding to an article by Myers et al. (2009), Becker et al. (2009) claimed that industry's Good Laboratory Practices (GLP)-compliant studies are superior to traditional academic peer-review in predicting the risk of toxic agents. I have read almost 30,000 experimental, etiologic, and epidemiologic papers (most in part), and it is evident that industry GLP studies do not report the same risks of a chemical when published in peer-reviewed studies from academia. This may be explained by biases in industry experiments and epidemiology, especially in design, due to the financial interests of industry sponsors—some receiving billions of dollars in revenue per chemical each year. For pharmaceuticals, dozens of published reviews show a strong correlation between industry sponsorship and findings of safety; I know of four such strong correlations in studies of industrial chemical risks (Bekelman et al. 2003; Fagin and Lavelle1999; Swaen and Meijers1988; vom Saal and Hughes 2005).

Becker et al. (2009) relied on a commentary by a former editor at the *Nature* research journals (Jennings 2006) to claim that peer-review gives inferior data compared with GLP studies. Actually, Jennings (2006) wrote about improving, not abandoning, peer review. He presented data showing that the long-term value of scientific papers in neuroscience (judged by experts) correlates with the quality of the journals in which they were published (based on impact factor). That is a cardinal finding because industry supports various journals and their scientific associations, but their GLP studies are rarely published in high-quality journals (again, based on my readings). Evidently, industry's GLP data are not reliable enough to publish, while financial independence of authors and editors, as well as peer review, are markers of good quality data.

Since the widespread experimental testing frauds at Industrial Bio-Test Laboratories (Schneider 1983) and Craven Laboratories (U.S. Environmental Protection Agency 1994), which generated the GLP reforms, industry has issued oceans of GLP-compliant studies for submission to regulatory agencies. Few are submitted for publication, but almost all (in my experience) are submitted to journals that publish many industry-sponsored studies.

Critically, industry and their regulatory agencies took the opportunity proferred by the requirement to comply with GLP to exclude almost all academic high-quality, non-GLP studies from risk assessments of existing chemicals (and the toxicity of new agents are primarily evaluated by the parties who want to sell it). For existing chemicals, I have always found that the effective toxicity doses in regulatory (GLP) studies are higher than those in the peer-reviewed literature, for several end points.

It is important for individuals who value the contributions that science makes to society (reliable data)—or those who are cautious about toxicity of low-dose and cocktail agents that may affect biochemical signals, especially during development—to continue lobbying public agencies to incorporate academia's peer-reviewed studies and to use disclosure of financial interests to give appropriate credence to industry's data in chemical risk assessments. I also call on independent academics to be less competitive and make their methods and data more freely available.

The author works for scientists and nongovernmental organizations, all of which have financial interests that align with public health.

Tony Tweedale
R.I.S.K. Consultancy
(Rebutting Industry Science with Knowledge)
Edinburgh, Scotland
E-mail: tony.tweedale@phonecoop.coop

References

Becker R, Janus E, White R, Kruszewski F, Brackett R. 2009. Good Laboratory Practices and safety assessments [Letter]. Environ Health Perspect 117:A482–A483.

Bekelman JE, Li Y, Gross CP. 2003. Scope and impact of financial conflicts of interest in biomedical research. JAMA 289(4):454–465.

Fagin D, Lavelle M, Center for Public Integrity. 1999. Toxic Deception: How the Chemical Industry Manipulates Science, Bends the Law and Endangers Your Health. 2nd ed. Monroe, ME:Common Courage Press.

Jennings CG. 2006. Quality and value: the true purpose of peer review. Nature; doi:10.1038/nature05032. Available: http://www.nature.com/nature/peerreview/debate/nature05032.html [accessed 19 November 2009].

Myers JP, vom Saal FS, Akingbemi BT, Arizono K, Belcher S, Colborn T, et al. 2009. Why public health agencies cannot depend on Good Laboratory Practices as a criterion for selecting data: the case of bisphenol A. Environ Health Perspect 117:309–315.

Schneider K. 1983. Faking it: the case against Industrial Bio-Test Laboratories. Amicus J (Spring):14–26.

Swaen GM, Meijers JM. 1988. Influence of design characteristics on the outcome of retrospective cohort studies. Br J Ind Med 45(9):624–629.

U.S. Environmental Protection Agency. 1994. Press Advisory: Craven Laboratories, Owner, and 14 Employees Sentenced for Falsifying Pesticide Tests. Washington, DC:U.S. Environmental Protection Agency.

vom Saal FS, Hughes C. 2005. An extensive new literature concerning low-dose effects of bisphenol A shows the need for a new risk assessment. Environ Health Perspect 113:926–933.

Good Laboratory Practices: Becker et al. Respond

doi:10.1289/ehp.0901755R

We appreciate the dialogue stimulated by our letter to the editor (Becker et al. 2009). Our intent was to respond only to Myers et al. (2009) regarding the purpose and function of Good Laboratory Practices (GLP) for weighting reliability of studies. Tyl (2009), in response to Myers et al. (2009), provided extensive point-by-point discussion of the specific studies.

In his letter, Tweedale implies that we argued to *a priori* exclude academic, non-GLP studies from risk assessments. To the contrary, we clearly stated that "[e]ach study, GLP and non-GLP, should be evaluated and weighed in accordance with fundamental scientific principles" (Becker et al. 2009). We fully agree with Tweedale that sources of funding should be disclosed, that researchers should "make their methods and data more freely available," and more industry-supported studies should be published in scientific journals. With respect to bias, Maurissen et al. (2005) and Barrow and Conrad (2006) discussed the spectrum of mechanisms in place to ensure the integrity of industry-sponsored research. Ultimately, all scientific research must stand on its merits. However, it is unscientific to eliminate or devalue any study based solely on the organization that conducted the study, the affiliation of an investigator, or the source of funding. The Society of Toxicology (2008) has stated this principle quite clearly: "[r]esearch should be judged on the basis of scientific merit, without regard for the funding source or where the studies are conducted (e.g., academia, government, or industry)."

Moreover, we did not seek to call into question scientific journal peer review per se, but instead to point out that whereas all study records and data from GLP investigations are available to regulatory agencies, rarely are such details made available as part of a peer-reviewed article published in a scientific journal. The point we wish to emphasize is that typical regulatory safety assessment studies conducted in accordance with GLP *a*) must follow agency test guidelines to assure use of relevant test systems, sufficient and applicable dosing protocols, and adequate dose groups and sizes, and *b*) must evaluate specific end points that regulatory organizations consider validated. Further, such GLP studies submitted to regulatory agencies generally include both a full study report and all raw data. This level of scientific rigor and the extensive data of a GLP study allow a regulatory agency to conduct a comprehensive review and to reach a fully independent conclusion. For these reasons, greater weight and confidence are generally afforded to GLP studies. Now, with the increasingly common practice of journals providing access to